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[Intervention Review]

Electrical stimulation for preventing and treating post-stroke shoulder pain

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ABSTRACT

Background

Shoulder pain after stroke is common and disabling. The optimal management is uncertain, but electrical stimulation (ES) is often used to treat and prevent pain.

Objectives

To determine the efficacy of any form of surface ES in the prevention and/or treatment of pain around the shoulder at any time after stroke.

Search methods

We searched the Cochrane Stroke Review Group trials register and undertook further searches of MEDLINE, EMBASE and CINAHL. Contact was established with equipment manufacturers and centres that have published on the topic of ES.

Selection criteria

We considered all randomised trials that assessed any surface ES technique (functional electrical stimulation (FES), transcutaneous electrical nerve stimulation (TENS) or other), applied at any time since stroke for the purpose of prevention or treatment of shoulder pain.

Data collection and analysis

Two reviewers independently selected trials for inclusion, assessed trial quality and extracted the data.

Main results

Four trials (a total of 170 subjects) fitted the inclusion criteria. Study design and ES technique varied considerably, often precluding the combination of studies. Population numbers were small. There was no significant change in pain incidence (Odds Ratio (OR) 0.64; 95% CI 0.19 to 2.14) or change in pain intensity (Standardised Mean Difference (SMD) 0.13; 95% CI -1.0 to 1.25) after ES treatment compared to control. There was a significant treatment effect in favour of ES for improvement in pain-free range of passive humeral lateral rotation (Weighted Mean Difference (WMD) 9.17; 95% CI 1.43 to 16.91). In these studies ES reduced the severity of glenohumeral subluxation (SMD -1.13; 95% CI -1.66 to -0.60), but there was no significant effect on upper limb motor recovery (SMD 0.24; 95% CI -0.14 to 0.62) or upper limb spasticity (WMD 0.05; 95% CI -0.28 to 0.37). There did not appear to be any negative effects of electrical stimulation at the shoulder.

Authors' conclusions

The evidence from randomised controlled trials so far does not confirm or refute that ES around the shoulder after stroke influences reports of pain, but there do appear to be benefits for passive humeral lateral rotation. A possible mechanism is through the reduction of glenohumeral subluxation. Further studies are required.

PLAIN LANGUAGE SUMMARY

Electrical stimulation for preventing and treating post-stroke shoulder pain

Electrical stimulation of muscles improves shoulder stiffness after a stroke but there is not enough evidence to prove whether it reduces shoulder pain. Patients who have a stroke (a sudden catastrophe in the brain either because an artery to the brain blocks, or because an artery in or on the brain ruptures and bleeds) often develop shoulder pain. This adds to the difficulties caused by the stroke. Pain in the shoulder can cause weakness, loss of muscle tone and loss of feeling. Electrical neuromuscular stimulation (ES) is done by applying an electrical current to the skin. This stimulates nerves and muscle fibres and may improve muscle tone, muscle strength, and reduce pain. The review found that shoulder stiffness improved after ES. No adverse effects were noted. The review also found there was not enough evidence to decide if ES can reduce shoulder pain or not. More research is needed.

BACKGROUND

Shoulder pain after stroke is common. Longitudinal studies have suggested that nearly three quarters of patients with hemiplegia suffer from shoulder pain during the twelve months after stroke (Roy 1994; Van Ouwenaller 1986; Wanklyn 1996). It is thought to be not just a marker of stroke severity (Roy 1995) but also to contribute significantly towards the poor functional recovery of the upper limb noted in rehabilitation studies (Nakayama 1994; Gowland 1982; Wyller 1997). The contribution of different aetiological factors remains controversial, but hemiplegic shoulder pain (HSP) has been associated with: reduced upper limb power, reduced shoulder shrug strength, abnormal muscle tone, glenohumeral subluxation, sensory inattention and sensory loss (Van Ouwenaller 1986; Wanklyn 1996; Roy 1994; Bohannon 1986; De Courval 1990; Zorowitz 1996) .

Electrical neuromuscular stimulation (ES) was first described over 35 years ago (Liberson 1961). Application of an electrical current to the skin stimulates lower motor nerves and muscle fibres resulting in improved contractility and greater muscle bulk (Albert 1984). Decreased spasticity and sensory cortex activation occurs via afferent neurone stimulation, with additional information being provided by the proprioceptive and visual perception of ES induced joint movement (Dimitriijevic 1994, Kumar 1995, Faghri 1997). Clinical reports have suggested that ES can improve: muscle group strength, joint malalignment, muscle tone, sensory deficits, pain -free range of passive humeral lateral rotation (PHLR) and self-reported pain intensity (Faghri 1994; Baker 1986; Prada 1995, Pandyan 1997). Most studies of HSP have pursued an analgesic effect through the use of ES to reduce glenohumeral subluxation and obtain better shoulder positioning.

Although ES is frequently administered via two methods, the distinction between them in the clinical setting is unclear. Functional electrical stimulation (FES) causes contraction of muscles in an organised fashion to facilitate the recovery of limb function, reduce spasticity or create better alignment of a joint's articular surfaces. Transcutaneous electrical nerve stimulation (TENS) is often used specifically as an analgesic technique to mask pain by giving lower intensity, higher frequency stimulation to cutaneous peripheral nerves without causing muscle contraction. However, regimens in between FES and TENS have been described, such as "high intensity TENS" (Leandri 1990). The treatment effects of these techniques also overlap e.g. FES has been described as analgesic (Faghri 1994), whilst TENS may reduce spasticity and improve function (Potisk 1995). Although there have been separate reviews of FES and TENS published which have considered treatment of HSP (Glanz 1996; Binder 1997; Granat 1994), the overlap between indications, techniques and outcomes would suggest that a complete review of ES for HSP can only be achieved if it is initially considered as a single intervention.

OBJECTIVES

The specific objective of this review was to determine the efficacy of any form of surface ES when used after stroke to prevent or treat shoulder pain and increase passive humeral lateral rotation.

METHODS

Criteria for considering studies for this review

Types of studies

All randomised controlled trials (RCTs) of ES versus a control were examined. Trials with quasi-randomised or systematic methods of treatment allocation were considered, as excluding them was likely to reduce the number of available studies. Individual trialists were contacted in cases where treatment allocation was uncertain. Blinding of outcome assessment was noted, but not used to exclude trials. It was not essential that the control group received a "sham" treatment, but note was made of any placebo.

Types of participants

Trials were considered which included patients of any age or gender with a clinical diagnosis of stroke, with or without a CT scan. There was no exclusion on the basis of previous stroke, but studies including subjects with other causes for their neurological injury were not used. Although HSP is a recognised term for shoulder pain after stroke (Wanklyn 1996), it was not essential for all subjects to have a hemiplegia, as there was likely to be some variation about this definition, and the effects of ES might be applicable to the broader stroke population. No predetermined time limit was set for how soon after stroke the ES was received.

Types of interventions

Only surface ES applications were considered, as invasive techniques are not widely available to the stroke population. Before the survey it was judged unlikely that there would be sufficient numbers of studies to consider differences in therapy such as electrode positioning, session duration and frequency, but this information was recorded. Studies which had ES as only one part of a multiple intervention package were not included e.g. ES and arm support together versus control. There was no exclusion according to authors' descriptions of ES technique used (i.e. ES, FES, high intensity TENS or standard TENS).

Types of outcome measures

From identified trials we extracted two types of outcome data to allow an intention-to-treat analysis:

- the proportion of subjects with shoulder pain in treatment and control groups;
- the changes in pain intensity levels relative to baseline in intervention and control groups, when a suitable measurement scale had been employed.

Pain intensity after stroke has often been recorded subjectively by simple word scales, numerical rating scale and visual analogue scale (Price 1994; Downie 1978; Melzack 1975). Shoulder pain has also been measured objectively by PHLR, recorded as degrees or percentages of maximum range (Bohannon 1986). It is not clear which method is best, as there are doubts about the reliability of subjective pain rating scales after stroke (Price 1999), and it is possible that objective ratings reflect factors other than shoulder pain intensity. Therefore these results should be interpreted with some caution, and the reliability of such measures will be left to the judgement of readers of this review. To consider whether there were any clinical implications from shoulder pain treatment by ES, additional data about changes in clinical features was extracted

from included studies e.g. upper limb function, glenohumeral subluxation, and spasticity. However, it is important to note that the non-analgesic effects of ES on upper limb recovery will be considered comprehensively by a separate review, and that the supplementary data included here is only to be viewed alongside the effects of ES on shoulder pain. Studies which considered changes in electromyographic activity as an objective measure of upper limb recovery were not included as their findings do not translate easily into clinical practice. Length of follow up was recorded. Note was made of whether assessors were blinded to treatment allocation.

Search methods for identification of studies

See: 'Specialized register' section in Cochrane Stroke Group

Relevant trials were identified in the Cochrane Stroke Group Trials Register, which was last searched by the Review Group Co-ordinator on 2 December 1999). We also searched: MEDLINE, CINAHL, CCTR (Appendix 1); and EMBASE (Appendix 2).

ES equipment manufacturers, established research centres and authors of review publications, case reports and original articles were contacted for identification of unpublished trials. They were identified by reference in the text of articles and a search of the world wide web databases NetFirst and BioMedNet, using the subject terms: electrical stimulation, transcutaneous electric nerve stimulation, neuromuscular stimulation and TENS. Material not printed in English was translated.

Data collection and analysis

Titles and abstracts of the electronic searches were screened by two independent reviewers, one with a background in stroke rehabilitation medicine, and one experienced in the application of ES after stroke for the recovery of wrist movement. The reviewers decided which trials met the inclusion criteria, and judged their methodological quality. Allocation concealment before randomisation was scored by the grading system used for Cochrane reviews i.e. adequate (A), unclear (B), inadequate (C), or not used (D). Checklists were used to independently record details of the randomisation method, study population, ES methods employed, length of follow up and outcome measures. Careful note was made of the proportions of subjects that completed the intervention period, and reasons why they left the study prematurely. Analysis was by "intention to treat". Extracted data was checked for agreement between reviewers. Trialists were contacted to provide missing data.

For each of the outcome measures a weighted treatment effect was calculated. The results were expressed as Peto odds ratio (OR) for the dichotomous variable: presence or absence of pain. Other outcomes were combined using the weighted mean difference (WMD) for identical measures and standardised mean difference (SMD) for different measures. When there was obvious variation between the WMD or SMD of individual studies ($p<0.1$), a random effects model was applied.

Sensitivity analyses were planned a priori for studies that had the following characteristics:

- true randomised versus quasi-randomised
- blinded versus unblinded treatment
- blinded versus unblinded outcome measurement
- placebo ("sham treatment") versus none
- FES versus TENS versus other ES
- prevention versus treatment studies
- time after stroke before application of ES

RESULTS

Description of studies

22 studies were identified by the search strategy. 16 of these were not considered suitable for a combination of the following reasons: not RCT, invasive ES technique and / or ES was not being used with the specific aim to treat or prevent shoulder pain. Only four trials (a total of 170 subjects) fitted the inclusion criteria (see table of included studies). Two further RCT were excluded as data has not yet become available to answer the specific questions addressed by this review (see table of excluded studies). Unpublished data has been included for Sonde 1998. No RCT study information was provided by manufacturers of ES equipment.

Age range was 45 to 84 years, most subjects being over 60 years. Gender distribution was nearly equal (45% males overall). Subjects with previous shoulder problems were usually excluded. All subjects were required to have a loss of motor function in the upper limb, although the definition of this varied between studies. Where the data were available, most subjects had ischaemic stroke confirmed by CT scan. Shoulder subluxation at recruitment was found in 5-40% of subjects.

There were 3 important differences between the populations of the included studies.

- The time between stroke and recruitment was <48hours for Linn 1999, an average of 16.5 days for Faghri 1994, an average of 12 weeks for Leandri 1990 (who consequently had a much higher number of subjects with shoulder subluxation entering the study), and an average of 8.7 months for Sonde 1998.
- Although Leandri 1990 clearly performed a study of treatment for the painful shoulder, Faghri 1994 did not record pain as a baseline measure, whilst Linn 1999 and Sonde 1998 had a mixed treatment and prevention population (predominantly without pain at entry). As it was not possible to distinguish clearly between ES intended to treat or prevent pain within these studies, the analysis could only examine new reports of pain and changes in pain intensity reports for any use of ES (i.e. prevention and treatment combined).
- Linn 1999 and Sonde 1998 used a subjective pain rating scale as a general assessment of pain (i.e. not restricted to active or passive motion). They acknowledged that some subjects with right side hemiparesis were excluded due to the effects of dysphasia. Faghri 1994 and Leandri 1990 used PHLR, which was also included by Linn 1999.

The ES technique used by each study was different. Linn 1999 and Faghri 1994 used stimulation intended to cause muscle contraction, whereas Leandri 1990 used a greater frequency set at the sensory threshold level (low intensity TENS group) and three times this amount (high intensity TENS group). It is unclear what degree of muscle activity resulted from the latter. Sonde 1998 refers to the treatment used as TENS, but has confirmed that it was applied with the intention of causing muscle contraction. Studies employed a 4-12 week program, but overall Linn 1999 had the most

sessions. All study subjects received "conventional" physiotherapy according to clinical need. Electrode positioning was commonly over supraspinatus and posterior deltoid, although Leandri 1990 placed them over the most painful points. It should be noted that 20% of the subjects treated by Sonde 1998 only received ES on the wrist extensors, as they did not have shoulder girdle weakness. No study used biofeedback.

In all studies outcome measures were made at the end of the intervention period and at a later stage. As these second set of measures were not after the same time interval (8 weeks - 3 years), represented a variable number of survivors, and were taken after unblinding, it was considered unreliable to combine them. Therefore they have not been used for the purposes of this review. Besides pain and PHLR, outcome measures used by these studies included recovery of arm movement, measurement of subluxation, and spasticity. These results were included but should be interpreted cautiously, as such features do not have simple associations with shoulder pain and this was not designed to be a comprehensive review of non-analgesic ES effects. The number of subjects in each study was small, and so the mean changes in these characteristics from baseline were calculated to reduce the influence of variations in initial levels of impairment. It was judged that the measurement of upper arm girth (Linn 1999) and humeral motion other than lateral rotation (Leandri 1990) would not contribute to the clinical implications of this review, as they were each used by only one study and have less clinical recognition. Due to design variations, it was not possible to combine the results from all studies for any single outcome.

Risk of bias in included studies

Randomisation

See characteristics of included studies table for details. It should be noted that Sonde 1998 finished recruitment prematurely and so unequal numbers were randomised to control and intervention groups. Due to the small sample sizes there were potentially confounding baseline characteristics:

- Sonde 1998 treatment group had a significantly higher Barthel ADL index.
- Linn 1999 treatment group had a significantly higher mean verbal rating of pain.

Blinding

Adequate concealment before randomisation was described by Linn 1999, but not Sonde 1998. Confirmation was not obtained from Leandri 1990 and Faghri 1994. Only Leandri 1990 used a sham treatment, although blinding subjects to allocation is difficult in ES studies because effects can be obvious during treatment (e.g. muscle contraction, paraesthesia). Linn 1999 and Leandri 1990 used blinded outcome measurement.

Losses to follow up

There were no losses to follow up for the first set of outcome measures in any study. No adverse effects were reported for any group of subjects.

Effects of interventions

New reports of shoulder pain and change in pain intensity level

Two trials (84 subjects, 49% of total) recorded reports of shoulder pain (Linn 1999, Sonde 1998), although this was only as a secondary outcome measure. There was no significant change in pain incidence after ES treatment compared to control (See Figure 1; OR 0.64; 95% CI 0.19 to 2.14). Due to heterogeneity between studies, the Mantel-Haenszel odds ratio was calculated, but this did not differ significantly (0.64; 95% CI 0.2 to 2.05). Although Linn 1999 concluded that there was not a significant difference in absolute pain level after ES, this was possibly confounded by the greater initial pain reports in the treatment group. When the mean change in pain intensity from baseline was calculated for control and treatment groups there was a significant effect in favour of ES for Linn 1999, although this result should be viewed cautiously, as the greater initial levels of pain in treatment group could augment any treatment effect. Accordingly Sonde 1998 did not reinforce this finding (See Figure 2; overall SMD 0.13; 95% CI -1.0 to 1.25). Sonde 1998 used a pain intensity scale that appears to be much more sensitive than that used by Linn 1999 (0-100 visual analogue scale compared to 0-4 verbal rating scale), but concerns have been raised about the ability of stroke patients to use similar visual analogue scales (Price 1999). This might be an explanation for the different results, in addition to the variation in population and intervention used.

Pain-free range of passive humeral lateral rotation comapred to baseline

Three trials (146 subjects, 86% of total) measured degrees of PHLR (Linn 1999, Leandri 1990 and Faghri 1994) before and after intervention. Overall there was a significant treatment effect in favour of ES (See Figure 3; WMD 9.17; 95% CI 1.43 to 16.91), but this was mainly because of the contribution from the High-TENS group (Leandri 1990). Linn 1999 found that there was a global reduction in lateral rotation for most subjects during the study (hence the negative mean change), but the development of restriction was still more marked in the control group. This finding may reflect the early recruitment of subjects into this study. Faghri 1994 compared the PHLR difference between left and right sides within each subject, demonstrating markedly less restriction on the side affected by stroke in the treatment group.

Motor score change from baseline

Three studies examining ES effects on shoulder pain after stroke also recorded the change in upper limb motor score after the intervention period (110 subjects, 65% of total) (Linn 1999, Faghri 1994, Sonde 1998). There was no significant effect of ES overall (See Figure 4; SMD 0.24; 95% CI -0.14 to 0.62). The results for Sonde 1998 are also presented according to initial upper limb impairment, which demonstrated a significant increase for those less severely affected subjects that received treatment (initial Fugl Meyer Score 30-50, or > 44% of score maximum). These subjects improved their score by mean of 6.4 (SD 4.38) points compared to 0.1 (SD 3.06) points in the control group (See Figure 5; less severely affected subgroup WMD 6.30; 95% CI 3.12 to 9.48).

Grading and measurement of subluxation compared to baseline

Two studies (33 subjects, 19% of total) recorded the amount of glenohumeral subluxation (Linn 1999, Faghri 1994). Both studies took measurements from a plane radiograph of the shoulder. Linn 1999 used an ordinal grading system of glenohumeral displacement, so that a more positive net result indicated greater subluxation. Faghri 1994 took direct measurement in millimetres, comparing difference between the affected and unaffected sides. The results suggest that ES reduces the severity of subluxation (See Figure 6; SMD -1.13; 95% CI -1.66 to -0.6).

Spasticity score change from baseline

Two studies (70 subjects, 41% of total) examined spasticity of the upper limb (Sonde 1998, Faghri 1994), and found no significant effect (See Figure 7; WMD 0.05; 95% CI -0.28 to 0.37). The scale used was the Ashworth Score, which is not a parametric scale, and interpretation of mean and SD should be viewed cautiously if future studies are to consider this aspect of impairment (Pandyan 1999).

Due to the small number of studies that could contribute to any one outcome measure, it was not possible to perform the proposed sensitivity analysis. The reviewers did not disagree about the data extracted from each study.

DISCUSSION

Electrical stimulation is not a new technique, but there is a lack of large randomised controlled trials to examine its effectiveness in the prevention and treatment of shoulder pain after stroke. It was disappointing that so many published works were case reports, or used non-standard outcome measures. The study by Linn 1999 has been the most rigorous in design so far, but was limited by small numbers and a variability in baseline measures. The methodological quality of studies was often suboptimal, and important differences in study design were noted. The small number of subjects that could be combined for any outcome measure makes it difficult to reach firm conclusions, and for most outcomes there is currently "no evidence for effect" rather than "evidence of no effect".

Overall, ES applied to the shoulder after stroke had no significant effect on subjective reports of pain, although there was a clear objective improvement in PHLR. This increase may be due to a reduction in glenohumeral subluxation, which was demonstrated by 2 studies (Faghri 1994,Linn 1999). These results suggest that when subluxation is a significant factor in the aetiology of shoulder pain, individuals may gain greater pain free movement at the shoulder following treatment with ES, although their background level of pain is not affected. As there are non-mechanical causes for shoulder discomfort it is reasonable that overall pain level does not significantly alter in the short term despite better congruity of the glenohumeral joint. It is uncertain how an increase in PHLR could enhance patients' quality of life, but some authors have recommended more widespread use of ES after observing improvement in upper limb positioning and facilitation of activities of daily living.

An improvement in upper limb function would be of more certain benefit. An increase in motor score was demonstrated by Faghri 1994 and Sonde 1998 (for the less severely affected group of subjects), but these results require cautious interpretation due to the very small unequal number of subjects. It is unclear why Sonde 1998 used certain values of the Fugl-Meyer Score to stratify the baseline, and no other study has yet presented their results according to initial upper limb impairment. From this review it is not possible to reach a broad conclusion about the use of ES specifically to improve upper limb function, as the search criteria only selected studies that had included pain as an outcome measure, and studies measured impairment rather than disability. Non-analgesic effects of ES will be the subject of a different review. Overall there would appear to be no effect of ES at the shoulder on upper limb motor function, but the stratification of subjects according to baseline measures should be considered for future studies considering this aspect of recovery. Any functional benefit from ES might be through improved muscle strength and indirectly through afferent stimulation resulting in enhanced cerebral plasticity, although the exact mechanism is unclear. There is increasing evidence for the use of early task-based physiotherapy in rehabilitation to guide plasticity (Feys 1998,Parry 1999), but the role of ES in combination with these approaches also remains unexplored. Despite these cautions ES in its different forms does not appear to have any harmful effects - although studies do not appear to have been very vigilant in looking for these. No outcome measure showed a significant deterioration.

ES (particularly TENS) is commonly used to treat rather than prevent shoulder pain after stroke, but this systematic review has found little evidence to recommend or discourage its routine use. Shoulder pain can be multifactorial (Wanklyn 1996), and it is probably unrealistic to expect one mode of treatment to be effective in all cases. Subjects frequently have pain at a second site in the upper limb, which could interfere with assessments. Therefore future studies may need to combine more types of treatment or be more selective about inclusion criteria, and broaden their pain survey. Pain measurement after stroke can be difficult, and can be confounded by the mixed populations entering studies. It is important that future work concentrates solely upon populations with (i.e. treatment) and without pain (i.e. prevention).

It will be difficult to compare between studies until there are widely accepted definitions of ES and TENS. In two studies (Sonde 1998, Leandri 1990) TENS was intended to cause muscle contraction, causing possible confusion with the intended action of ES. The frequency and duration of treatment was variable, but there were insufficient numbers in this review to reach any conclusion about the best application. Therapeutic regimes should also consider the progress made during treatment, so that ES is halted at a defined physiological end-point rather than simply the end of a standard interval. Currently it is not possible to recommend a treatment regimen, as the average number of sessions varied from 12 - 112, and a dose-response relationship has not emerged in terms of treatment duration, frequency or technique. There are fewer results in favour of TENS than high-intensity TENS or ES, but the poor distinction between these makes it impossible to make recommendations about therapeutic options. There has been no study looking at the ideal time to apply ES after stroke, and there were insufficient trials eligible for this review to allow this important question to be considered by a sensitivity analysis.

Finally it should be considered that the initial benefits of any ES may fade with time i.e. improvement may be quicker than control, but not reach a greater level overall. All included studies took later measures which have suggested that there is decay after

treatment finishes, but these results have not been included as they were taken after variable time intervals when subjects had been lost to follow up, and groups had been unblinded. The length of follow up in future studies needs to be extended, and current conclusions only apply up until the end of the ES treatment period. Outcome measures should also include other important aspects of recovery (e.g. psychological, resources). To avoid confounding the combination of future studies it will also be necessary to record in some way what intervention the control group receive, as "standard therapy" can vary widely between centres and within centres over time.

AUTHORS' CONCLUSIONS

Implications for practice

There is currently no evidence to confirm or refute that ES can influence reports of shoulder pain after stroke. There are significant benefits for passive humeral lateral rotation. A possible mechanism is through the reduction of glenohumeral subluxation. Evidence is not currently available to demonstrate an improvement in the quality of life. A particular ES technique cannot be recommended, but this limited data suggests that it is a low risk intervention that can be used at any time after stroke.

Implications for research

There is a need for adequately powered RCTs to examine the role of ES after stroke for prevention of shoulder pain starting during the acute stage of stroke, and as one component of a treatment protocol for the painful shoulder during rehabilitation. This limited search also suggests that a study is required to examine improvement of upper limb recovery from the acute stage of stroke in a population stratified according to initial upper limb impairment. The distinctions between different types of ES technique are not clear, and evidence of a difference in clinical effects is required. A broader perspective of upper limb pain may need to be included in future studies, and further basic work is required to demonstrate the validity of scales used to record pain after stroke.

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CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Faghri 1994

Methods	Randomisation not known. Unclear whether outcome measurement adequately blinded. No sham treatment.
Participants	n = 26; age mean 67 years; 58% male. Single centre; all inpatients; mean 16.5 days after stroke. CT scan not done on all subjects; 65% left hemiplegia. No baseline pain measurement.
Interventions	No sham treatment vs FES 6 weeks. 2 electrodes placed over supraspinatus and posterior deltoid. Sessions increasing from 1.5 to 6 hours per day.; 7 days per week; average sessions received unknown. No biofeedback.
Outcomes	Measures at 6 weeks: difference between arms of pain-free range of humeral lateral rotation; arm function (Bobath assessment); tone (0-4 grading); radiological glenohumeral separation in millimetres; and EMG activity. Measures also taken at 12 weeks (not used).
Notes	It is unclear subjects with previous shoulder problems were excluded. All subjects had intial flaccid paralysis. As there was no baseline pain measurement it is unclear whether the subjects were being treated fro pain or receiving prevention.

Risk of bias

Bias	Authors' judgement	Support for judgement

Faghri 1994 *(Continued)*

Allocation concealment?	Unclear risk	B - Unclear

Leandri 1990

Methods	Randomisation not known. Blinded outcome measure. Sham treatment was used in the control group.
Participants	n = 60; age mean 66 years; 27% male. Single centre; all inpatients; mean 12 weeks after stroke. CT Scan all subjects (no haemorrhage) 67% right hemiparesis. All subjects had shoulder pain at the start of the study. 40% with shoulder subluxation.
Interventions	Sham treatment vs high intensity TENS vs low intensity TENS 4 weeks. 2 electrodes placed on most tender areas of shoulder girdle. Session duration unknown; 3 sessions / week; 12 sessions per subject on average. No biofeedback.
Outcomes	Measures at 4 weeks: pain-free range of glenohumeral motion, including lateral rotation. Measures also taken at 8 weeks (not used).
Notes	Ischaemic stroke only. All subjects had motor impairment (not defined), but were mobile with assistance.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Unclear risk	B - Unclear

Linn 1999

Methods	Randomization by opaque sealed envelopes Blind outcome measure No sham treatment in control group
Participants	n = 40; age mean 72 years; 45% male. Single centre; inpatients within 48 hours of stroke CT Scan all subjects (7.5% haemorrhage) 22.5% right hemiparesis. 2 / 20 control subjects and 9 / 20 intervention subjects had some shoulder pain at the start of the study. 5% with shoulder subluxation.
Interventions	No sham treatment vs electrical stimulation 4 weeks (not FES or TENS). Electrodes placed supraspinatus and posterior deltoid Session duration 0.5 - 1 hour; 28 sessions / week; 112 sessions per subject on average. No biofeedback.
Outcomes	Measures at 4 weeks: verbal rating scale of pain (0-4), radiological grading of shoulder subluxation , pain-free range of lateral rotation, upper limb section of Motor Assessment Scale, upper arm girth. Measures also taken at 3 months after stroke (not used).

Linn 1999 *(Continued)*

Notes	Exclusions were subjects with previous shoulder pathology, no significant motor deficit (<= 2 on the Manual Muscle Test), communication difficulties (not defined). It is not possible to define this study as prevention or treatment of pain due to the pain reports by some subjects at entry.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Sonde 1998

Methods	Randomisation by random number generation. Not blind outcome assessment. No sham treatment.
Participants	n = 44; age mean 72 years; 61% male; Single centre; all outpatient treatment; mean 8.7 months after stroke; all subjects had CT scan (% haemorrhage unknown); 57% right hemiparesis; 4 control subjects and 2 intervention had pain at the start. Single centre outpatient treatment. There are 8 more subjects in intervention group as study was stopped prematurely.
Interventions	No sham treatment vs low frequency TENS (with muscle contraction) 3 months; 60 minutes for 5 days / week ; mean number of sessions 63 (3.4); electrodes on wrist extensors and in 80% also on shoulder (if there was shoulder girdle weakness); no biofeedback.
Outcomes	Measures at 12 weeks: visual analogue scale for pain (0-100), Fugl-Meyer motor score, Modified Ashworth Scale of spasticity. 3 year follow up data (not used).
Notes	Only first ever stroke included, but no exclusions given. TENS group had significantly higher Barthel Score at baseline. Unequal numbers in control and TENS groups as study finished early. Subgroup analysis done on less severly affacted motor group.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	High risk	C - Inadequate

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Chantraine 1996	Abstract only. Data not available.
Chantraine 1999	19 / 120 subjects without stroke (isolated stroke data not available). Systematic unblinded randomisation method used (alternate hospital admissions into each group).

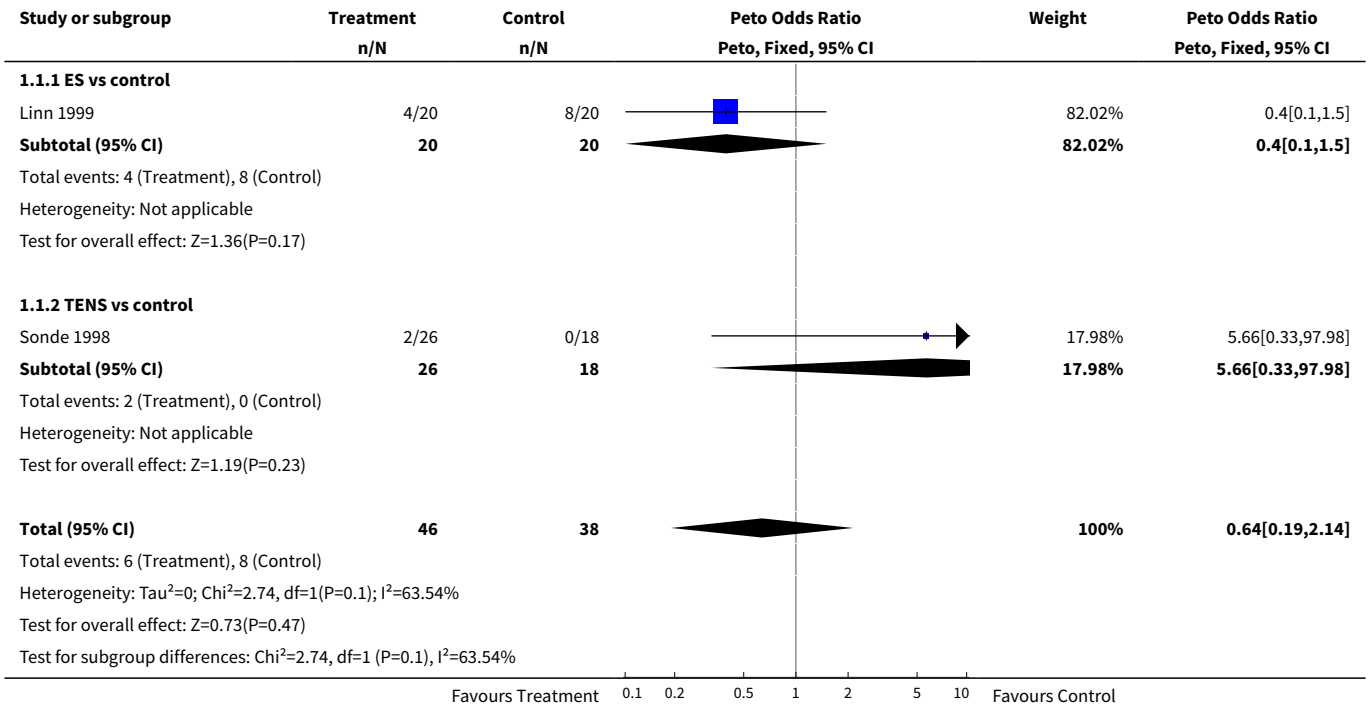
DATA AND ANALYSES

Comparison 1. Any ES in the prevention and treatment of shoulder pain after stroke

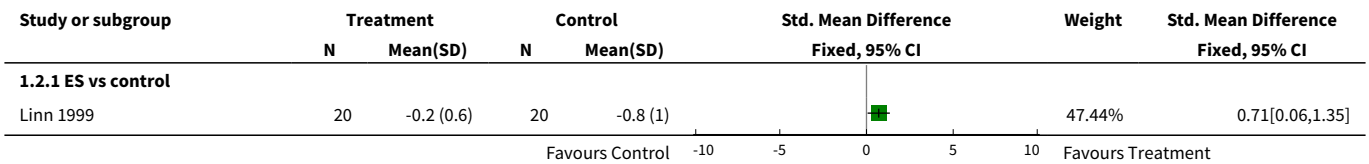
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 New reports of shoulder pain	2	84	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.64 [0.19, 2.14]
1.1 ES vs control	1	40	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.40 [0.10, 1.50]
1.2 TENS vs control	1	44	Peto Odds Ratio (Peto, Fixed, 95% CI)	5.66 [0.33, 97.98]
2 Pain intensity rating change from baseline	2	84	Std. Mean Difference (IV, Fixed, 95% CI)	0.10 [-0.34, 0.54]
2.1 ES vs control	1	40	Std. Mean Difference (IV, Fixed, 95% CI)	0.71 [0.06, 1.35]
2.2 TENS vs control	1	44	Std. Mean Difference (IV, Fixed, 95% CI)	-0.44 [-1.05, 0.16]
3 PHLR compared to baseline	3	146	Mean Difference (IV, Fixed, 95% CI)	6.53 [4.71, 8.35]
3.1 ES vs control	1	40	Mean Difference (IV, Fixed, 95% CI)	8.3 [-4.44, 21.04]
3.2 High intensity TENS vs control	1	40	Mean Difference (IV, Fixed, 95% CI)	12.53 [9.50, 15.56]
3.3 TENS vs control	1	40	Mean Difference (IV, Fixed, 95% CI)	2.75 [0.43, 5.07]
3.4 FES vs control	1	26	Mean Difference (IV, Fixed, 95% CI)	21.0 [1.18, 40.82]
4 Motor score change from baseline	3	110	Std. Mean Difference (IV, Fixed, 95% CI)	0.24 [-0.14, 0.62]
4.1 ES vs control	1	40	Std. Mean Difference (IV, Fixed, 95% CI)	0.06 [-0.56, 0.68]
4.2 TENS vs control	1	44	Std. Mean Difference (IV, Fixed, 95% CI)	0.18 [-0.42, 0.79]
4.3 FES vs control	1	26	Std. Mean Difference (IV, Fixed, 95% CI)	0.63 [-0.17, 1.42]
5 Motor score change from stratified baseline	1	44	Mean Difference (IV, Fixed, 95% CI)	1.46 [0.01, 2.91]
5.1 TENS vs control (less severely affected: F-M 30-50)	1	21	Mean Difference (IV, Fixed, 95% CI)	6.30 [3.12, 9.48]
5.2 TENS vs control (more severely affected: F-M 0-29)	1	23	Mean Difference (IV, Fixed, 95% CI)	0.20 [-1.43, 1.83]
6 Glenohumeral subluxation compared to baseline	2	66	Std. Mean Difference (IV, Fixed, 95% CI)	-1.13 [-1.66, -0.60]

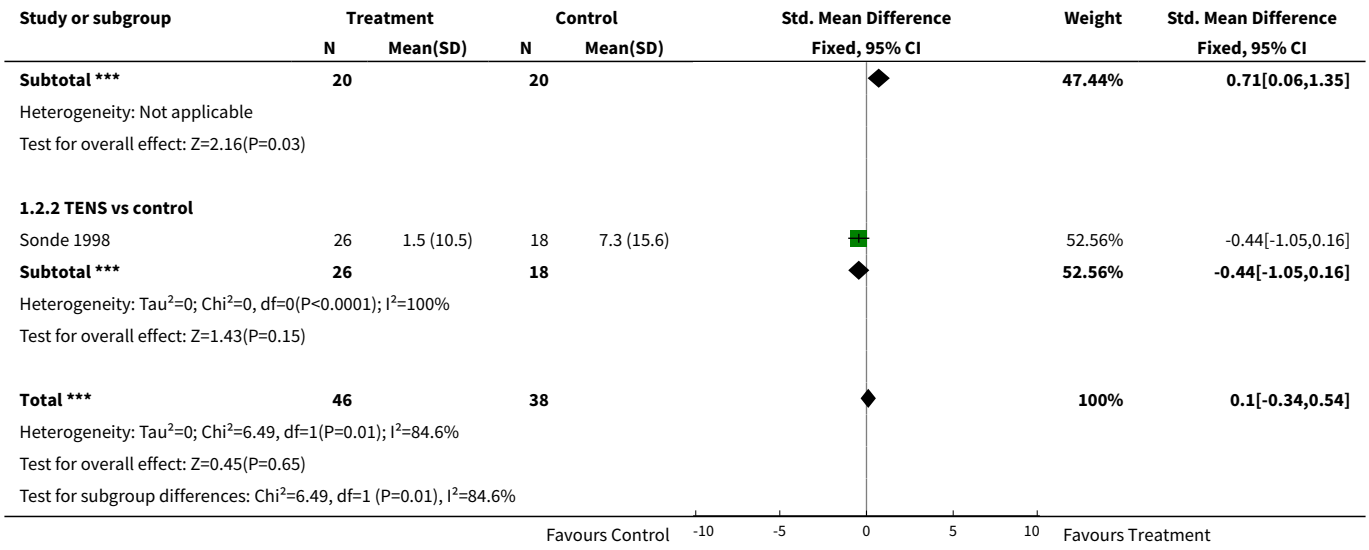
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
6.1 ES vs control	1	40	Std. Mean Difference (IV, Fixed, 95% CI)	-0.88 [-1.54, -0.23]
6.2 FES vs control	1	26	Std. Mean Difference (IV, Fixed, 95% CI)	-1.60 [-2.50, -0.70]
7 Spasticity score change from baseline	2	70	Mean Difference (IV, Fixed, 95% CI)	0.05 [-0.28, 0.37]
7.1 TENS vs control	1	44	Mean Difference (IV, Fixed, 95% CI)	-0.1 [-0.55, 0.35]
7.2 FES vs control	1	26	Mean Difference (IV, Fixed, 95% CI)	0.21 [-0.26, 0.68]

Analysis 1.1. Comparison 1 Any ES in the prevention and treatment of shoulder pain after stroke, Outcome 1 New reports of shoulder pain.

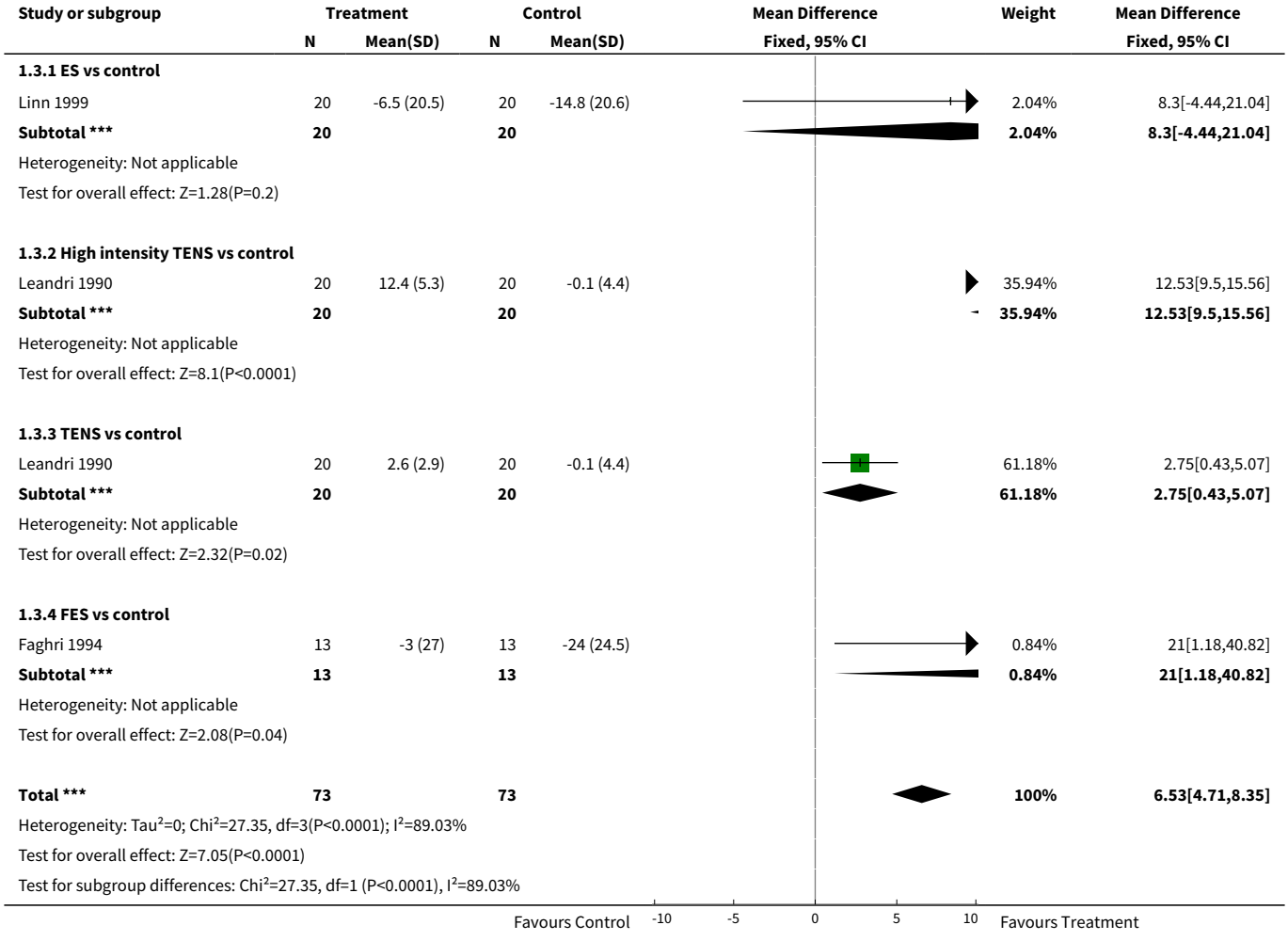


Analysis 1.2. Comparison 1 Any ES in the prevention and treatment of shoulder pain after stroke, Outcome 2 Pain intensity rating change from baseline.



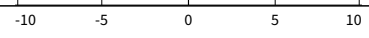


Analysis 1.3. Comparison 1 Any ES in the prevention and treatment of shoulder pain after stroke, Outcome 3 PHLR compared to baseline.



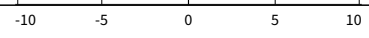
Analysis 1.4. Comparison 1 Any ES in the prevention and treatment of shoulder pain after stroke, Outcome 4 Motor score change from baseline.

Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Fixed, 95% CI	Weight	Std. Mean Difference Fixed, 95% CI
1.4.1 ES vs control							
Linn 1999	20	2 (2.3)	20	1.9 (2.3)		37.39%	0.06[-0.56,0.68]
Subtotal ***	**20**		**20**			**37.39%**	**0.06[-0.56,0.68]**
Heterogeneity: Not applicable							
Test for overall effect: Z=0.2(P=0.84)							
1.4.2 TENS vs control							
Sonde 1998	26	3.8 (15.7)	18	0.8 (16.6)		39.62%	0.18[-0.42,0.79]
Subtotal ***	**26**		**18**			**39.62%**	**0.18[-0.42,0.79]**
Heterogeneity: Not applicable							
Test for overall effect: Z=0.6(P=0.55)							
1.4.3 FES vs control							
Faghri 1994	13	1.4 (1.3)	13	0.7 (1)		22.99%	0.63[-0.17,1.42]
Subtotal ***	**13**		**13**			**22.99%**	**0.63[-0.17,1.42]**
Heterogeneity: Not applicable							
Test for overall effect: Z=1.55(P=0.12)							
Total ***	**59**		**51**			**100%**	**0.24[-0.14,0.62]**
Heterogeneity: Tau^2=0; Chi^2=1.26, df=2(P=0.53); I^2=0%							
Test for overall effect: Z=1.24(P=0.21)							
Test for subgroup differences: Chi^2=1.26, df=1 (P=0.53), I^2=0%							



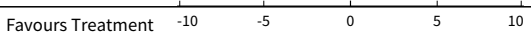
Analysis 1.5. Comparison 1 Any ES in the prevention and treatment of shoulder pain after stroke, Outcome 5 Motor score change from stratified baseline.

Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
1.5.1 TENS vs control (less severely affected: F-M 30-50)							
Sonde 1998	12	6.4 (4.4)	9	0.1 (3.1)		20.67%	6.3[3.12,9.48]
Subtotal ***	**12**		**9**			**20.67%**	**6.3[3.12,9.48]**
Heterogeneity: Tau^2=0; Chi^2=0, df=0(P<0.0001); I^2=100%							
Test for overall effect: Z=3.88(P=0)							
1.5.2 TENS vs control (more severely affected: F-M 0-29)							
Sonde 1998	14	1.5 (1.7)	9	1.3 (2.1)		79.33%	0.2[-1.43,1.83]
Subtotal ***	**14**		**9**			**79.33%**	**0.2[-1.43,1.83]**
Heterogeneity: Not applicable							
Test for overall effect: Z=0.24(P=0.81)							
Total ***	**26**		**18**			**100%**	**1.46[0.01,2.91]**
Heterogeneity: Tau^2=0; Chi^2=11.18, df=1(P=0); I^2=91.06%							
Test for overall effect: Z=1.98(P=0.05)							
Test for subgroup differences: Chi^2=11.18, df=1 (P=0), I^2=91.06%							



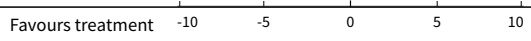
Analysis 1.6. Comparison 1 Any ES in the prevention and treatment of shoulder pain after stroke, Outcome 6 Glenohumeral subluxation compared to baseline.

Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Fixed, 95% CI	Weight	Std. Mean Difference Fixed, 95% CI
1.6.1 ES vs control							
Linn 1999	20	0.3 (0.4)	20	0.7 (0.6)		65.65%	-0.88[-1.54,-0.23]
Subtotal ***	**20**		**20**			**65.65%**	**-0.88[-1.54,-0.23]**
Heterogeneity: Not applicable							
Test for overall effect: Z=2.65(P=0.01)							
1.6.2 FES vs control							
Faghri 1994	13	-3.5 (5.4)	13	5.9 (6)		34.35%	-1.6[-2.5,-0.7]
Subtotal ***	**13**		**13**			**34.35%**	**-1.6[-2.5,-0.7]**
Heterogeneity: Not applicable							
Test for overall effect: Z=3.47(P=0)							
Total ***	**33**		**33**			**100%**	**-1.13[-1.66,-0.6]**
Heterogeneity: Tau^2=0; Chi^2=1.59, df=1(P=0.21); I^2=36.99%							
Test for overall effect: Z=4.19(P<0.0001)							
Test for subgroup differences: Chi^2=1.59, df=1 (P=0.21), I^2=36.99%							



Analysis 1.7. Comparison 1 Any ES in the prevention and treatment of shoulder pain after stroke, Outcome 7 Spasticity score change from baseline.

Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
1.7.1 TENS vs control							
Sonde 1998	26	0 (0.7)	18	0.1 (0.8)		53.1%	-0.1[-0.55,0.35]
Subtotal ***	**26**		**18**			**53.1%**	**-0.1[-0.55,0.35]**
Heterogeneity: Not applicable							
Test for overall effect: Z=0.44(P=0.66)							
1.7.2 FES vs control							
Faghri 1994	13	1.1 (0.4)	13	0.9 (0.8)		46.9%	0.21[-0.26,0.68]
Subtotal ***	**13**		**13**			**46.9%**	**0.21[-0.26,0.68]**
Heterogeneity: Not applicable							
Test for overall effect: Z=0.87(P=0.39)							
Total ***	**39**		**31**			**100%**	**0.05[-0.28,0.37]**
Heterogeneity: Tau^2=0; Chi^2=0.87, df=1(P=0.35); I^2=0%							
Test for overall effect: Z=0.27(P=0.78)							
Test for subgroup differences: Chi^2=0.87, df=1 (P=0.35), I^2=0%							



APPENDICES

Appendix 1. MEDLINE search strategy

MEDLINE (Ovid) 1966-98, CINAHL (Ovid) 1982-98 and the Cochrane Controlled Trials Register (CCTR/CENTRAL), employing the search strategy:
1. electric stimulation/
2. electric stimulation therapy/
3. transcutaneous electric nerve stimulation/
4. electric$ stimulation.tw
5. neuromuscular stimulation.tw
6. (FES or TENS or ES).tw
7. 1 or 2 or 3 or 4 or 5 or 6
8. exp cerebrovascular disorders/
9. cerebrovasc$.tw
10. stroke$.tw
11. hemiplegia/
12. (hemipleg$ or hemipar$).tw
13. 8 or 9 or 10 or 11 or 12
14. arm/
15. shoulder/
16. shoulder joint/
17. (arm$ or shoulder$ or upper limb$ or upper extremity$).tw
18. 14 or 15 or 16 or 17
19. pain/
20. pain$.tw
21. 19 or 20
22. 7 and 13 and 18 and 21

Appendix 2. EMBASE search strategy

EMBASE (OVID) 1980-98, employing the search strategy:
1. electrostimulation/
2. electrostimulation therapy/
3. nerve stimulation/
4. transcutaneous nerve stimulation/
5. electric$ stimulation.tw
6. neuromuscular stimulation.tw
7. (FES or TENS or ES).tw
8. 1 or 2 or 3 or 4 or 5 or 6 or 7
9. exp cerebrovascular disease/
10. hemiplegia/
11. hemiparesis/
12. (cerebrovasc$ or stroke$ or hemipar$ or hemipleg$).tw
13. 9 or 10 or 11 or 12
14. arm/
15. arm movement/
16. arm muscle/
17. shoulder/
18. shoulder pain/
19. shoulder injury/
20. shoulder girdle/
21. shoulder hand syndrome/
22. frozen shoulder/
23. (arm$ or shoulder$ or upper limb$ or upper extremity$).tw
24. 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23
25. pain/
26. pain$.tw
27. 25 or 26
28. 8 and 13 and 24 and 27

WHAT'S NEW

Date	Event	Description
6 August 2008	Amended	Converted to new review format.

CONTRIBUTIONS OF AUTHORS

Dr Christopher Price will be the named guarantor for the review, and his contribution to date has been the conception, design and development of the protocol. He will be responsible for the development, analysis and interpretation of the full review.

Dr David Pandyan has assisted in the design of the protocol, and also with the search strategy, retrieval of papers, abstracting data, and contacting authors for further information.

DECLARATIONS OF INTEREST

None

SOURCES OF SUPPORT

Internal sources

- University of Newcastle, UK.
- Northumbria Healthcare NHS Trust, UK.

External sources

- No sources of support supplied

INDEX TERMS

Medical Subject Headings (MeSH)

Electric Stimulation Therapy [*methods]; Randomized Controlled Trials as Topic; Range of Motion, Articular; Shoulder Pain [etiology] [prevention & control] [*therapy]; Stroke [*complications]

MeSH check words

Humans